



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Cheung, W.K. et al.

Serial No.: 10/037,369

Art Unit: 1654

Filed

: November 7, 2001

Examiner: Meller, M.V.

For

AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, D.C. 20231 on

May 20, 2003

Myra H. McCormack

(Name of applicant, assignee, or Registered Representative)

(Signature)

(Dete of Signature)

RECEIVED

MAY 2 3 2003

TECH CENTER 1600/2900

Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §\$1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

#10 D.G.) 10/10/10

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. In accordance with \$1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under \$1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in \$1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under \$1.114, no additional fee is required. In accordance with \$1.129(a), this Information Disclosure Statement is being filed in connection with \(\square\$ the first or Second After Final Submission, therefore: Statement in Accordance with \$1.97(e) (attached); П or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in \$1.17(p). X In accordance with \$1.97(c), this Information Disclosure Statement is being filed after the period set forth in \$1.97(b) above but before the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311, or an action that otherwise closes prosecution and that it is accompanied by one of: M Statement in Accordance with \$1.97(e) (attached); or

Please charge Deposit Account No. 10-
0750/ / the fee of $$180.00$ as set forth in
\$1.17(p).
In accordance with \$1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311 but before the payment of the Issue Fee.
Applicant(s) hereby petition(s) for consideration of this
Information Disclosure Statement. Included are: Statement in
Accordance with §1.97(e) as set forth below and the fee of
\$180.00 as set forth in \$1.17(p).
☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
Copies of references listed on the attached Form PTO- 1449 are enclosed herewith EXCEPT THAT:
In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
There are no listed references which are not in the English language.
The relevance of those listed references which are not in the English language is as follows:

Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D. Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D. Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT1531/MHM. This form is submitted in triplicate. Respectfully submitted, Reg. No. 36602 Attorney for Applicants Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-6932 DATED: lay 20, 2003 4 -



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 1 of 2

a collection of information unless it displays	a vand OMB control number.	
Application Number	10/037,369	
Filing Date	November 7, 2001	
First Named Inventor	Cheung, W.K.	
Group Art Unit	1654	
Examiner Name	Meller, M.V.	
Attorney Docket Number	ORT-1531	

	U.S. PATENT DOCUMENTS					
Examiner	Cite	U.S. Patent Do	ocument		Date of Publication	Pages, Columns, Lines,
		Kind Code ²		Name of Patentee or Applicant	of Cited Document	where relevant passages
Initials	No. ¹	Number	(if known)	of Cited Document	mm-dd-yyyy	or relevant figures appear
					+ RF(CEIVED
				<u> </u>	, the	
					MAY	2 3 2003
						2 9 2003
					TECH CEN	TER 1600/2900
					ILONICE	11LN 1000/2300

FOREIGN PATENT DOCUMENTS Foreign Patent Document Date of Publication Pages, Columns, Lines, of Cited Document where relevant Name of Patentee or passages or relevant T⁶ Cite Examiner mm-dd-yyyy **Applicant of Cited Document** figures appear Initials Number⁴ KindCode5 9707788 03-06-1997 WO A Alkernes Inc. wo 0061169 Ortho McNeil Pharm, Inc. 10-19-2000 Α Α 08-14-1997 wo 9728828 Amgen Boulder Inc. wo 0013710 Α Scios Inc. 03-16-2000 wo Α 04-14-1983 8301198 Berg Kurt Frimann

Examiner	Date
Signature	Considered

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 2 of 2

a conection of information timess it displays a valid OMB control furnities.		
Application Number	10/037,369	
Filing Date	November 7, 2001	
First Named Inventor	Cheung, W.K.	
Group Art Unit	1654	_
Examiner Name	Meller, M.V.	_
Attorney Docket Number	ORT-1531	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
		CHEUNG, W. et al: "Pharmacokinetics and pharmacodynamics of epoetin alfa once weekly and three times weekly". European Journal of Clinical Pharmacology, vol. 57, no. 5, August 2001 (2001-08), pages 411-418, ISSN: 0031-6970.	
		TROXEL, T.R., et al: "Ovulation and reproductive hormones following steroid pretreatment, calf removal and GnRH in postpartum suckled beef cows". Journal of Animal Science, vol. 51, no. 3, 1980, pages 652-659. ISSN:0021-8812.	
		RECEIVED	
		MAY 2 3 2003	
		TECH CENTED 1600/0000	

Examiner	Date	
Signature	Considered	
	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

MAY 2 2 2003 W

Examiner

Signature

SUBMISSION UNDER MPEP 609 D

Page 1 of 1

Application Number	10/037,369
Filing Date	November 7, 2001
First Named Inventor	Cheung, W.K.
Group Art Unit	1654
Examiner Name	Meller, M.V.
Attorney Docket Number	ORT-1531

Examiner Initials No.! Name of Patentee or Applicant of Cited Document Of Cited Document Number (if known) Pages, Columns, Lines, where relevant passages or relevant figures appear

FOREIGN PATENT DOCUMENTS Foreign Patent Document Pages, Columns, Lines, where relevant passages Name of Patentee or or relevant figures Cite Examiner Applicant of Cited Document Office³ Number⁴ KindCode⁵ appear Initials No.1 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), T² Cite No.¹ title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), Examiner volume-issue number(s), publisher, city and/or country where published Initials* PCT International Search Report, PCT/US02/36300, March 19, 2003.

Date

Considered



Docket No. ORT-1531

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Cheung, W.K. et al.

Serial No. : 10/037,369

Art Unit: 1654

Filed

: November 7, 2001

Examiner: Meller, M.V.

For

: AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, D.C. 20231 on

May 20 20 U3

Myra H. McCormack
plicant, assignee, or Registered Representative)

Myalulumau (signature) May 22,2003

RECEIVED

MAY 2 3 2003

TECH CENTER 1600/2900

Commissioner for Patents Washington, D.C. 20231

STATEMENT UNDER 37 C.F.R. §1.97(e)

In accordance with 37 C.F.R. \$1.97(e), certification is hereby made that:

Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or

No item of information contained in the Information

Disclosure Statement was cited in a communication from a foreign

patent office in a counterpart foreign application, and, to the

knowledge of the undersigned after making reasonable inquiry, no item

of information contained in this Information Disclosure Statement, was known to any individual designated in \$1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Myra H. McCormack

Reg. No. 36602

Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6932
DATED: 20 May 2003

RECEIVED

MAY 2 3 2003

TECH CENTER 1600/2900